

<b>Department of Origin:</b> Integrated Healthcare Services	<b>Effective Date:</b> 09/15/22
<b>Approved by:</b> Medical Policy Quality Management Subcommittee	<b>Date approved:</b> 03/08/22
<b>Clinical Policy Document:</b> Obstructive Sleep Apnea, Non-Surgical Treatment	<b>Replaces Effective Clinical Policy Dated:</b> 11/03/21
<b>Reference #:</b> MC/C011	<b>Page:</b> 1 of 6

**PURPOSE:**

The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

**POLICY:**

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

**GUIDELINES:**

Medical Necessity Criteria – Must satisfy the following: I, and any of II - V

- I. Member is diagnosed with obstructive sleep apnea (OSA) based on sleep study results (in-home or sleep center); and
- II. Requesting *positive airway pressure* (PAP) device – must satisfy any of the following: A or B
  - A. Initial request – must satisfy any of the following: 1 or 2
    1. Member is diagnosed with moderate to severe OSA as defined by an *AHI* score of greater than or equal to 15; or
    2. Member is diagnosed with mild OSA as defined by an *AHI* score of greater than or equal to 5 and less than 15, and documentation supports any of the following: a - g
      - a. History of stroke; or
      - b. Hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg); or
      - c. Ischemic heart disease; or
      - d. Symptoms of impaired cognition, mood disorders, or insomnia; or
      - e. Excessive daytime sleepiness; or
      - f. Greater than 20 episodes of oxygen desaturation (ie, oxygen saturation of less than 85 %) during a full night sleep study, or any one episode of oxygen desaturation (ie, oxygen saturation of less than 70 %); or
      - g. Oxygen saturation less than or equal to 88% for > 5 minutes.
  - B. Replacement request – must satisfy the following: 1 and 2, and either 3 or 4
    1. Documentation of *adherence* with therapy; and
    2. The device is *malfunctioning*; and
    3. Member has had current *PAP* device for greater than or equal to 5 years; or
    4. The device is out of warranty.

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- III. Requesting custom fit (may be prefabricated or custom-fabricated) oral appliance – must satisfy any of the following: A or B
- A. Initial request – must satisfy the following: 1, and any of 2 or 3
    - 1. Must be prescribed by an MD or DO and fitted by a qualified, licensed dentist (DDS or DMD); and
    - 2. Member has mild to moderate OSA as defined by an *AHI*, *RDI* or *REI* score of less than 30; or
    - 3. *PAP* has been tried with well-supported follow-up including involvement by qualified sleep specialist, and has clearly failed due to any of the following: a - h
      - a. Failure to improve symptoms after a minimum of one month trial; or
      - b. Difficulty tolerating pressure; or
      - c. Intolerance of nasal or mouth interface; or
      - d. Nasal irritation; or
      - e. Claustrophobia; or
      - f. Dry mouth; or
      - g. Removal of *PAP* device unintentionally during sleep; or
      - h. Documentation that *PAP* is contraindicated.
  - B. Replacement request – must satisfy all of the following: 1, and 2 or 3
    - 1. Documentation of regular follow-up within the previous 12 months; and
    - 2. Member has had current oral appliance for greater than or equal to 3 years; or
    - 3. There has been a change in the member’s condition.
- IV. Claims for *PAP* and oral device will be allowed within the same 12-month period with supporting documentation, submitted by a qualified sleep specialist, reflecting that the member requires both due to failure of *PAP* alone.
- V. Repeat sleep studies are not medically necessary unless there is documentation that it is being performed for any of the following: A - D
- A. To determine the effectiveness of a new device; or
  - B. For persistent symptoms of daytime sleepiness; or
  - C. Substantial weight loss (at least 10% of body weight); or
  - D. Change in clinical status (eg, worsening or improvement, abnormal findings on *PAP* download)

**EXCLUSIONS (not limited to):**

Refer to member’s Certificate of Coverage or Summary Plan Description.

The following are considered investigative (see Investigative List): I - XX

- I. Adjustable Tongue-Advancement Device (such as, but not limited to, The Advance System)

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II. Apnea-triggered Muscle Stimulation (does not apply to hypoglossal nerve stimulation, see MC/1012 Neurostimulation, Hypoglossal Nerve )

III. Cardiac (Atrial) Pacing

IV. Cautery-Assisted Palatal Stiffening Operation (CAPSO)

V. Epiglottidectomy/Partial Epiglottidectomy

VI. Expansion Sphincteroplasty

VII. Genioplasty and Genial Tubercle Advancement

VIII. Glossectomy, partial

IX. Injection Snoreplasty

X. Laser Assisted Uvuloplasty (LAUP)

XI. Mandibular Distraction Osteogenesis (MDO)

XII. Nasal Dilators

XIII. Palatal Implants (Pillar Procedure)

XIV. Radiofrequency Volumetric Tissue Reduction of the palate, tongue, or uvula (Somnoplasty/Coblation)

XV. Remotely Controlled Mandibular Positioner

XVI. Tongue-based Reduction Surgery

XVII. Tongue-Based Suspension (such as, but not limited to, The Repose or AIRvance System)

XVIII. Transpalatal Advancement Pharyngoplasty (TAP)

XIX. Winx Therapy System/Oral Pressure Therapy

XX. Obstructive Sleep Apnea (OSA) oral appliance to restore proper mandibular alignment after use of overnight sleep apnea appliance, for prevention of temporomandibular joint dysfunction (such as, but not limited to, the Direct AM Positioner, Morning Repositioner [SomnoMed])

**DEFINITIONS:**

Adherence:  
5/7 nights or 70%

Apnea:  
Transient cessation of respiration

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Apnea Hypopnea Index (AHI):

Average number of episodes of *apnea* and/or *hypopnea* per hour of sleep

Epworth Sleepiness Scale:

A scale use to indicate the likelihood of falling asleep in the following commonly encountered situations by assigning a score between 0 (none) and 3 (high chance). The scores are summed; a total greater than 10 is considered abnormal.

- Sitting and reading
- Watching TV
- Sitting, inactive, in a public place, i.e., theater
- As a passenger in a car for an hour without a break
- Lying down to rest in the afternoon when circumstances permit
- Sitting and talking to someone
- In a car, while stopped for a few minutes in traffic

Hypopnea:

Abnormally slow or especially shallow respiration

Malfunctioning:

The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

Obstructive Sleep Apnea Types (from AASM):

- *AHI* of 5-14: Mild OSA; Involuntary sleepiness during activities that require little attention (eg, watching TV, reading)
- *AHI* of 15-29: Moderate OSA; Involuntary sleepiness during activities that require some attention (eg, meetings, presentations)
- *AHI* of 30 or greater: Severe OSA; Involuntary sleepiness during activities that require more active attention (eg, talking, driving)

Positive Airway Pressure (PAP):

A PAP machine works by gently blowing pressurized room air through the airway at a pressure high enough to keep the throat open. This pressurized air acts as a sort of splint. The pressure is set according to the patient's needs, high enough to ensure that the airway is fully open when the sleeper inhales but not so high that the sleeper is disturbed by the sensation. (The obstructions of the airway occur during sleep but not during waking hours partly because all muscles, including the muscles in the throat, relax during sleep.) The delivery of positive airway pressure is available in many forms, such as basic CPAP, bilevel positive airway pressure (BiPAP), automatically titrating positive airway pressure, and demand positive airway pressure.

Rapid eye movement (REM) RDI:

*RDI* during REM sleep

Respiratory Disturbance Index (RDI):

Average number of respiratory disturbances per hour (*apneas*, *hypopneas*, and respiratory event-related arousals [RERAs])

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Respiratory Event Index:

Average number of respiratory disturbances per hour (*apneas*, *hypopneas*, and respiratory event-related arousals [RERAs])

**BACKGROUND:**

Obstructive Sleep Apnea (OSA) is a disorder in which complete or partial obstruction of the airway during sleep causes loud snoring, oxyhemoglobin desaturations, and frequent arousals.

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Prior Authorization: No

**CODING:**

HCPCS: 2021

PAP

E0470 Respiratory assist device, bi-level pressure capability, without backup rate feature, used without non- invasive interface

E0601 Continuous positive airway pressure (CPAP) device

Oral device/appliances

D7880 Occlusal orthotic device

D8210 Removable appliance therapy

D9947 Custom sleep apnea appliance fabrication and placement

E0485 Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment

E0486 Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

K1027 Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment

**REFERENCES:**

1. Integrated Healthcare Services Process Manual UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. Clinical Policy: MC/B002 Orthognathic Surgery
4. Clinical Policy: MC/C007 Obstructive Sleep Apnea, Surgical Treatment in Adults
5. Clinical Policy: MP/D004 Durable Medical Equipment, Prosthetics, Orthotics and Supplies
6. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med.* 2009;5(3):263-276. Retrieved from <https://aasm.org/clinical-resources/practice-standards/practice-guidelines/>. Accessed 12-21-21.
7. Patil SP, Ayappa IA, Caples SM, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med.* 2019;15(2):335-343. Retrieved from <https://aasm.org/clinical-resources/practice-standards/practice-guidelines/>. Accessed 12-21-21.
8. Ramar K, Dort LC, Katz SG, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. *J Clin Sleep Med.* 2015;11(7):773-827. Retrieved from <https://aasm.org/clinical-resources/practice-standards/practice-guidelines/>. Accessed 12-21-21.
9. US Food and Drug Admin. Code of Federal Regulations Title 21, Volume 8, Subpart A, Sec 803.3, (k)<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=803&showFR=1>. Accessed 12-21-21.
10. U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS). Decision memo for continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA) (CAG-0093R2). Medicare Coverage Database. Baltimore, MD: CMS; October 30, 2001.- Retrieved from <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=19&fromdb=true> Accessed 12-21-21.

**DOCUMENT HISTORY:**

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## Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

*We* will:

- Provide free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provide free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *COC*, *your* id card, or [aspirushealthplan.com](http://aspirushealthplan.com).

If *you* believe that *we* have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a grievance with:

Nondiscrimination Grievance Coordinator  
Aspirus Health Plan, Inc.  
PO Box 1062  
Minneapolis, MN 55440  
Phone: 1. 866.631.5404 (TTY: 1.866.631.8597)  
Fax: 763.847.4010  
Email: [customerservice@aspirushealthplan.com](mailto:customerservice@aspirushealthplan.com)

*You* can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help *you*.

*You* can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

## Language Assistance Services

**Albanian:** KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 1.866.631.8597).

تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية 1.866.631.5404 (رقم هاتف الصم والبك : 1.866.631.8597) متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف  
**Arabic**

**French:** ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.866.631.5404 (ATS : 1.866.631.8597).

**German:** ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 1.866.631.8597).

**Hindi:** \_यान द\_ : य\_द आप िहंदी बोलते ह\_ तो आपके िलए मु\_त म\_ भाषा सहायता सेवाएं उपल\_ध ह\_। 1-800-332-650 (TTY: 1.866.631.8597) पर कॉल कर\_।

**Hmong:** LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 1.866.631.8597).

**Korean:** 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 1.866.631.8597) 번으로 전화해 주십시오.

**Polish:** UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 1.866.631.8597).

**Russian:** ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 1.866.631.8597).

**Spanish:** ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 1.866.631.8597).

**Tagalog:** PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 1.866.631.8597).

**Traditional Chinese:** 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY : 1.866.631.8597)

**Vietnamese:** CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 1.866.631.8597).

**Pennsylvania Dutch:** Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 1.866.631.8597).

**Lao:** ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທສ 1.866.631.5404 (TTY: 1.866.631.8597).